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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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VIKSNINS HARRIS & PADYS PLLP
P.O. BOX 111098
ST. PAUL, MN 55111-1098

EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/574,460	APICELLA ET AL.	
	Examiner	Art Unit	
	Yong D. Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30,34,37-39,43,46-48 and 54-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30, 34, 37-39, 43, 46-48 and 54-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on December 4, 2007, amending the specification, has been entered. The amendment filed on August 17, 2007, amending claims 30, 39, and 48 and adding claims 59-72, has been entered.

Claims 30, 34, 37-39, 43, 46-48 and 54-72 are pending and are under consideration.

Response to Arguments

Applicant's amendment and arguments filed on August 17, 2007, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59, 64 and 69 and claims 60-63, 65-68 and 70-72 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 59, 64 and 69 recite the phrases "the isolated DNA sequence encoding a lipooligosaccharide-synthesis gene G polypeptide (LsgG) from *Haemophilus influenzae* is encoded by pGEMLOS-4,pGEMLOS-5 or pGEMLOS-7". It is not clear to the Examiner as to how a DNA sequence can be encoded by a plasmid, pGEMLOS-4,pGEMLOS-5 or pGEMLOS-7. Examiner requests clarification of the above phrase.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30, 34, 37-39, 43, 46-48 and 54-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 30, 34, 37-39, 43, 46-48 and 54-72 are drawn to a method of producing a lipooligosaccharide (LOS) or complex carbohydrate by culturing a *Salmonella minnesota* comprising a polynucleotide encoding an undecaprenyl-phosphate N-acetyl glucosaminyl phosphate transferase (rfe) that is part of the *S. Minnesota* genome, wherein said bacteria is **(1)** transformed with a polynucleotide encoding a naturally-occurring lipooligosaccharide-synthesis gene G polypeptide (lsgG) from *H. influenzae*, including any or all variants, recombinants and mutants thereof or **(2)** transformed with pGEMLOS-4, pGEMLOS -5 or pGEMLOS -7 which encodes a lsgG, wherein a terminal

heptose of a lipopolysaccharide (LPS) or LOS core structure of said gram-negative bacterial species is modified by the addition of N-acetyl glucosamine. It is noted that MPEP 2111.01 states that "[d]uring examination, the claims must be interpreted as broadly as their terms reasonably allow." In this case, the examiner has broadly interpreted "(rfe) that is part of the *Salmonella minnesota* genome" as a *S. minnesota* transformed with a heterologous *rfe* gene and a *S. minnesota* comprising an endogenous *rfe* gene since a polynucleotide becomes part of the host's genome upon transformation. Also, the claims also encompass polynucleotides encoding naturally-occurring LsgG. Alternative form of genes may result in at least one mutation in the nucleic acid sequence, which are found in nature. Alleles may result in altered mRNAs or polypeptides whose structure or function may or may not be altered. Alleles may result in altered mRNAs or polypeptides whose structure or function may or may not be altered. The specification does not provide any specific information about the structure of the naturally occurring (alleles) of the LsgG gene (i.e. where in the regions within which mutations are likely to occur) nor discloses any function for the naturally occurring variants. There is no description of the mutational sites that exist in nature, and there is no description of how the structure of LsgG relates to the structure of any naturally occurring alleles. The general knowledge in the art concerning alleles does not provide any indication of how one allele is representative of unknown alleles. The nature of alleles is such that they are variant structures, and in the present state of the art, structure of one does not provide guidance to the structure others.

Therefore, the claims encompass a method of producing LOS by transforming *S. minnesota* with any or all polynucleotides encoding a LsgG from *H. influenzae*, including any or all variants, mutants and recombinants thereof, wherein said *S. minnesota* endogenously comprises any or all polynucleotides encoding a rfe or are transformed with any or all polynucleotides encoding a rfe from another including any or all variants, mutants and recombinants thereof. Therefore, the claims are drawn to a method of producing LOS using a *S. minnesota*, wherein (A) said bacterium is transformed with a genus comprising any or all polynucleotides encoding a LsgG from *H. influenzae,* having any structure and/or (B) said bacterium endogenously produces rfe or is transformed with a genus of any or all polynucleotides encoding a rfe from any source having any structure.

The specification only describes a method of producing specific LOS described in Table 2 and 3 by transforming *S. minnesota* with a polynucleotide encoding lsgG isolated from *H. influenzae (*pGEMLOS-4, pGEMLOS-5 or PGEMLOS-7), wherein the polynucleotide encoding rfe is endogenous to the bacterium. This one example is not enough and does not constitute a representative number of species to describe the whole a method of making LOS in *S. minnesota* by using a genus comprising any or all polynucleotides encoding rfe or genus comprising any or all polynucleotides encoding lsgG. There is no evidence on the record of the relationship between the structure of the polynucleotide encoding lsgG in pGEMLOS-4 and the structure of any or all polynucleotides encoding lsgG, including any or all recombinants, mutants and variants thereof. Similarly, there is no evidence on the record of the relationship between the

structure of the polynucleotide encoding rfe endogenous to *S. minnesota* and the structure of any or all polynucleotide encoding rfe, including any or all recombinants, mutants and variants thereof. Therefore, the specification fails to describe a representative species of the genus comprising any or all polynucleotides encoding rfe and genus comprising any or all polynucleotides encoding lsgG and used to transform a *S. minnesota* to produce LOS.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 30, 34, 37-39, 43, 46-48 and 54-72.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the previous Office Action, applicants have traversed the above rejection. Applicants should note that the rejection has been amended in light of the amendment of the claims.

Applicants argue that since the claims have been amended to recite that the DNA sequence encoding rfe is part of the *S. Minnesota genome* and that LsgG is encoded by an isolated DNA sequence encoding a naturally-occurring LsgG from *H. influenzae* or that *LsgG* gene is encoded by an isolated DNA sequence encoding a pGEMLOS-4, pGEMLOS-5 or pGEMLOS-7, the claims meet the written description

requirement. Examiner respectfully disagrees. (1) Regarding the *rfe* gene, the examiner has broadly interpreted "(rfe) that is part of the *Salmonella minnesota* genome" as a *S. minnesota* transformed with a heterologous *rfe* gene and a *S. minnesota* comprising an endogenous *rfe* gene since a polynucleotide becomes part of the host's genome upon transformation. (2) Regarding the LsgG gene, claims 30, 34, 37-39, 43, 46-48 and 54-58 are drawn to a polynucleotide encoding a naturally-occurring LsgG from *H. influenzae*. Alternative form of genes may result in at least one mutation in the nucleic acid sequence, which are found in nature. Alleles may result in altered mRNAs or polypeptides whose structure or function may or may not be altered. Alleles may result in altered mRNAs or polypeptides whose structure or function may or may not be altered. The specification does not provide any specific information about the structure of the naturally occurring (alleles) of the LsgG gene (i.e. where in the regions within which mutations are likely to occur) nor discloses any function for the naturally occurring variants. There is no description of the mutational sites that exist in nature, and there is no description of how the structure of LsgG relates to the structure of any naturally occurring alleles. The general knowledge in the art concerning alleles does not provide any indication of how one allele is representative of unknown alleles. The nature of alleles is such that they are variant structures, and in the present state of the art, structure of one does not provide guidance to the structure others. The recitation of "LsgG" and "rfe" fails to provide a sufficient description of the claimed genus of polynucleotides encoding polypeptides as it merely describes the functional features of the encoded polypeptides of the genus without providing any definition of the

structural features of the species within the genus. The CAFC in UC California v. Eli Lilly, (43 USPQ2d 1398) stated that: "in claims to genetic material, however a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus." Similarly with the claimed genus of "LsgG" and "rfe" polynucleotides, the functional definition of the genus does not provide any structural information commonly possessed by members of the genus which distinguish the protein species within the genus from other proteins such that one can visualize or recognize the identity of the members of the genus. Further, as discussed in the written description guidelines, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. **Thus, when there is substantial**

variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. Satisfactory disclosure of a representative number depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. In the instant case the claimed genus includes species which are widely variant in structure. As such, the disclosure of solely functional features present in all members of the genus is sufficient to be representative of the attributes and features of the entire genus.

Hence the rejection is maintained.

Claims 59-72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plasmids. Since the plasmids are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmid's sequence is not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of

35 U.S.C. 112 may be satisfied by a deposit of the plasmids. The specification does not disclose a repeatable process to obtain the plasmid and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of the plasmids should have been made in accordance with 37 CFR 1.801-1.809.

It is noted that if applicants have deposited the plasmids, they must be public available. If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be available to the public under the conditions specified in 37 CFR 1.808, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that: 1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request; 2. upon granting of the patent the strain will be available to the public under the conditions specified in 37 CFR 1.808; 3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and 4. the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30, 34, 37-39, 43, 46-48 and 54-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin et al. in view of Swierzko et al.

Claims 30, 34, 37-39, 43, 46-48 and 54-58 are drawn to a method of producing LOS or complex carbohydrate and a method of adding a N-acetyl glucosamine to a terminal heptose of a LOS or LPS core structure using a *S. minnesota* containing a polynucleotide encoding a rfe that is part of the *S. Minnesota* genome and transformed with pGEMLOS-4 (7.4 kb *bam*HI-*pst*I DNA *H. influenzae lsg* locus) or pGEMLOS-7 (2.8 kb *sph*I-*pst*I DNA H. *influenzae lsg* locus).

McLaughlin et al. (form PTO-1449) discloses to a method of producing LOS, a complex carbohydrate, using an *E. coli* transformed with a polynucleotide encoding a lsgG from *H. influenzae,* wherein said *E. coli* endogenously comprises a polynucleotide encoding a rfe polynucleotide (pages 165-166). McLaughlin et al. also discloses a 7.4 kb *bam*HI-*pst*I fragment from the *H. influenzae lsg* locus (PGEMLOS-4) and a 2.8 kb *sph*I-*pst*I fragment from the *H. influenzae lsg* locus (pGEMLOS-7), see Figure 1 on page 168. McLaughlin et al. also discloses addition of N-acetyl glucosamine to a terminal heptose of a LOS or LPS core structure in *E. coli* and that it is most probable that various sugar transferases expressed from *H. influenzae lsg* locus are responsible for

the modification the LPS in *E. coli* (page 172). Regarding regulation of *rfe* by lsgG, regulation of rfe by LsgG is an inherent property of LsgG, which would flow naturally when both polynucleotides are present.

With this teaching at hand, one having ordinary skill in the art would have looked to apply the method of McLaughlin et al. in other bacterium comprising a terminal heptose molecule.

The difference between the reference of McLaughlin et al. and the instant invention is that the reference of McLaughlin et al. does not teach a method of producing LOS in *Salmonella minnesota*.

Swierzko et al. (cited previously on form PTO-892) discloses that *S. minnesota* bears a terminal heptose molecule, similar to *E. coli*, and discloses using this bacterium in synthesizing LPS (pages 3216-3217). Brade et al. (form PTO-1449) discloses a method of transforming *S. minnesota* with recombinant polynucleotides (page 483).

Therefore, in combining the teachings of McLaughlin et al. Swierzko et al. and Brade et al., it would have been obvious to one having ordinary skill in the art modify the method of McLaughlin et al. by transforming *S. minnesota* et al. with either of the lsg fragment from *H. influenzae*. One of ordinary skill in the art would have been motivated to transform *S. minnesota* with the lsg of McLaughlin et al. in order to modify the terminal heptose of *S. minnesota*, thereby producing chimeric LPS/LOS specific to *H. influenzae*, useful in construction of carbohydrate-based vaccines. One of ordinary skill in the art would have had a reasonable expectation of success since McLaughlin et al. teaches a lsg gene that is possibly responsible for the modification the LPS,

Swierzko et al. teaches using *S. minnesota* to produce LOS and Brade et al. teaches transformation of *S. minnesota*.

Therefore, the above references render claims 30, 34, 37-39, 43, 46-48 and 54-72 *prima facie* obvious to one of ordinary skill in the art.

In response to the previous Office Action, applicants have traversed the above rejection. Applicants should note that the rejection has been amended in light of the amendment of the claims.

Applicants argue that since McLaughlin et al. could not determine the functions of the putative products encoded by the ORFs, there is no motivation to isolate one of the ORFs, such as the ORF encoding LsgG and transform it into a different type of bacteria. Examiner respectfully disagrees. Since the claims are not drawn to a polynucleotide consisting of the lsgG gene and McLaughlin et al. teaches that various sugar transferases expressed from the *H. influenzae lsg* locus is responsible for the modification of LPS in E. coli and that it is likely that the lsg locus should contain a series of genes coding for sugar transferases (page 172), one having ordinary skill in the art would have been motivated to transform other bacterium comprising a terminal heptose molecule, such as *S. minnesota*, with the lsg of McLaughlin et al.

Applicants also argue that it would not have been obvious to substitute *Salmonella* for *E. coli* since (1) it was quite surprising that one could start with a *Salmonella* bacterium, transform a gene from another type of bacteria and have the foreign protein, LsgG, sucessfully regulate another gene (rfe) such that an acceptor molecule is added to a core region to make the chimeric carbohydrate since in nature

Salmonella does not place any additional sugars onto to the core region and (2) Mclaughlin et al. does not suggest that it would have been desirable or advantageous to have expressed the *H. influenzae* lipooligosaccharide synthesis gene LsgG in *Salmonella*. Examiner respectfully disagrees. (1) It appears that applicants are arguing that there was unexpected result of adding sugars to the core region of Salmonella. If this is true, applicants are urged to submit a declaration. But more importantly, the claims are drawn to a method of using a *S. minnesota* which produces rfe endogenously and applicants on page 9 of the Remarks (filed on August 17, 2007) state that the specification supports the instant claims, that the "*rfe* gene being endogenous to Salmonella bacterial production". Therefore, since applicants state that S. minnesota can "endogenously contain an rfe gene" (page 9 of the Remarks) and expression of heterologouos genes (such as the lsg locus of McLaughlin et al.) is well known and taught in the art (Brade et al.), Examiner takes the position that it was not surprising to that one could start with a *Salmonella* bacterium, transform a gene from another type of bacteria and have the foreign protein, LsgG, sucessfully regulate another gene (rfe) such that an acceptor molecule is added to a core region to make the chimeric carbohydrate. (2) With the teaching of McLaughlin et al., one having ordinary skill in the art would have looked to apply the method of McLaughlin et al. in other bacterium comprising a terminal heptose molecule, such as a *S. Minnesota,* in order to produce chimeric LPS/LOS specific to *H. influenzae*, useful in construction of carbohydrate-based vaccines. One of ordinary skill in the art would have had a reasonable expectation of success since McLaughlin et al. teaches a lsg gene that is possibly

responsible for the modification the LPS, Swierzko et al. teaches using *S. minnesota* to produce LOS and Brade et al. teaches transformation of *S. minnesota*.

Hence the rejection is maintained.

None of the claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Yong D Pak/
Primary Examiner, Art Unit 1652